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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,023	03/12/2004	Daniel Hawiger	RUJ-001CNCP2	9210

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
10/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,023	HAWIGER ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-28,55 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-28,55,56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/9/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election of human DEC-205 in the reply filed on 5/20/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-12,14-28,46,55,56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the conjugate recited in the claimed method.

The instant claims recite use of an antiDEC antibody wherein said antibody would encompass antibodies which bind mutants and variants or alleles of the two known DEC-205 amino acid sequences disclosed in the specification and wherein the identity of said mutants and variants is unpredictable. However, only the specific amino acid sequences encoding full length murine and human DEC-205 protein are disclosed in the specification.

In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991).

Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated:

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments, applicant has not addressed the above issue *as per recited in said rejection in the previous Office Action.* The

amendment to the claims has addressed the issue of "mammalian DEC-205" as per previously recited in the claims.

4. Claims 1-12,14-28,46,55,56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V.

Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the conjugate recited in the claimed method.

The instant claims recite use of a dendritic cell maturation factor. Whilst the specification discloses several examples of such molecules, the term would encompass variants and mutants of said molecules. The term would encompass said molecules derived from any mammalian species wherein the identity of said molecules in the vast majority of mammals is unknown and unpredictable. The claims would also encompass a vast collection of unknown molecules with the functional activity recited in the claims wherein the identity of such molecules is unknown and structurally unpredictable (mimetics, nonprotein molecules, etc).

In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli

Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991).

Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated:

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicant comments, the instant claims recite use of a dendritic cell maturation factor. Whilst the specification and cited patent discloses several examples of such molecules, the term would encompass variants and mutants of said molecules. The term would encompass said molecules derived from any mammalian species wherein the identity of said molecules in the vast majority of mammals is unknown and unpredictable. The claims would also encompass a vast collection of unknown molecules with the functional activity recited in the

claims wherein the identity of such molecules is unknown and structurally unpredictable (mimetics, nonprotein molecules, etc). Furthermore, even among the specific reagents cited in the specification, there is no structurally similarity among the cited agents such that the structure of the genus of dendritic cell maturation factors would be unpredictable.

5. Regarding the application of prior art, the scope of the claimed inventions are not disclosed in the parent applications to which priority is claimed and therefore the claimed inventions are not entitled to priority to said applications. In addition, the claimed inventions also lack written description in the parent applications for the reasons elaborated above. In addition, it is also noted that human DEC-205 of the sequence disclosed in the specification is not disclosed in the parent applications.

Regarding applicants comments, applicant has not addressed where claims 24-28,55,56 find support in the parent applications. There is no support for the method of claim 24 (a method for increasing the persistence of MHC class I antigen complexes in a mammal) in the parent applications. Regarding applicants comments as pertaining to claims 1-12,14-23, none of the cited portions of the parent applications disclose the claimed method of "promoting highly efficient antigen presentation" (as per recited in claims 1 and 2) wherein the term is defined as per section [0088] of the specification.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1,3-7,10,11,14-17,19,21-25,46,55 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonifaz et al.

Bonifaz et al. disclose in vivo subcutaneous administration to a mammal of a non-replicating antigen/anti DEC-205 monoclonal antibody covalent conjugate and a dendritic cell maturation factor (agonist antiCD40 antibody) wherein dendritic cells are contacted by the aforementioned reagents in vivo (see abstract, page 1628, page 1629, first column, third paragraph, Figure 4, pages 1632-35). The antigen is conjugated to the heavy and light chain of the antibody. The mammals were vaccinated with a single dose of conjugate (see Figure 4). The mammals were vaccinated with 4 micrograms of conjugate (see Figure 4) without an adjuvant. The functional properties recited in the claims are inherent properties of the aforementioned method because it uses the same reagents as the claimed method.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1,3-12,14-28,46,55,56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonifaz et al. in view of Germeraad et al. (US 2005/0037001).

Bonifaz et al. disclose in vivo subcutaneous administration to a mammal of a nonreplicating antigen/anti DEC-205 monoclonal antibody covalent conjugate and a dendritic cell maturation factor (agonist antiCD40 antibody) wherein dendritic cells are contacted by the aforementioned reagents in vivo (see abstract, page 1628, page 1629, first column, third paragraph, Figure 4, pages 1632-35). The functional properties recited in the claims are properties of the aforementioned method because it uses the same reagents as the claimed method. The antigen is conjugated to the heavy and light chain of the antibody. The mammals were vaccinated with a single dose of conjugate (see Figure 4). The mammals were vaccinated with 4 micrograms of conjugate (see Figure 4) in

the absence of antigen. Bonifaz et al. do not teach the claimed methods using a tumor antigen or humanized antibody. Germeraad et al. disclose that in vivo administration of conjugates of a humanized antibody against a dendritic cell molecule and a tumor antigen can be used to generate an immune response to said antigen (see [0028],[0029],[0031],[0033],and [0039]). A routineer would have determined the optimal amount and schedule of administration of a particular conjugate for administration using routine experimentation. The antibody can be single chain (aka scFv, see [0031]). The conjugate can be administered mucosally (see [0039], wherein mucosal administration would induce mucosal immunity). Germeraad et al. disclose that said treatment would be used to treat tumors (see [0038]), wherein treatment of tumors encompasses killing/reduction of tumor mass. The various functional parameters recited in the claims result from treatment with the reagents recited in the claims. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Bonifaz et al. disclose in vivo administration to a mammal of an antigen/anti DEC-205 monoclonal antibody covalent conjugate and a dendritic cell maturation factor (agonist antiCD40 antibody) wherein dendritic cells are contacted by the aforementioned reagents in vivo whilst Germeraad et al. disclose that in vivo administration of conjugates (including via IV or mucosal route) of a humanized antibody scFv against a dendritic cell molecule and a tumor antigen can be used to treat tumors bearing said antigen wherein a routineer would have determined the optimal amount of a particular conjugate for administration using routine experimentation. One of ordinary skill in the art would have been motivated to do the aforementioned because Bonifaz disclose that their method results in improved immune responses to an administered antigen. In addition, in KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art**

would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill".

10. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonifaz et al. in view of Germeraad et al. (US 2005/0037001) as applied to claims 1,3-12,14-28,46,55,56 above, and further in view of Lasky et al. (US 6,117,977)
The previous rejection renders obvious the claimed invention except for the use of the conjugate recited in claim 2. Lasky et al. teach bispecific conjugates wherein one arm of the conjugate recognizes a type C lectin (aka such a DEC-205, see column 1, last
paragraph) and the other arm recognizes a desired antigen (see column 30, last paragraph). The method of Bonifaz et al. uses two different antibodies wherein a routineer would have produce a bispecific conjugate as per Lasky et al. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because the previous rejection renders obvious the claimed invention except for the use of the conjugate recited in claim 2, whilst Lasky et al. teach bispecific conjugates wherein one arm of the conjugate recognizes a type C lectin (aka such a DEC-205) and the other arm recognizes a desired antigen and the method of Bonifaz et al. uses two different antibodies. One of ordinary skill in the art would have been motivated to do the aforementioned because the method of Bonifaz uses two different antibodies and Lasky et al. teach bispecific conjugates wherein one arm of the conjugate recognizes a type C lectin (aka such a DEC-205) and the other arm recognizes a desired antigen. In addition, in KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**.

11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Ron Schwadron, Ph.D
Primary Examiner, Art Unit 1644